Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) A process for producing parenterally~~, preferably by injection,~~ administrable microparticles containing a biologically active substance, ~~which process comprises~~ comprising:

a) preparing an aqueous starch solution comprising starch which (i) has an amylopectin content exceeding 85% by weight, in which the molecular weight of the ~~said~~ amylopectin has been reduced such that at least 80% by weight of the ~~material~~ amylopectin is within the range of 10-10,000 kDa; ~~, and~~ which (ii) has an amino acid nitrogen content of less than 50 μg per [g] gram dry weight of starch, the starch concentration of the solution being at least 20% by weight; and which (iii) essentially lacks covalently bonded hydroxyethyl groups;

b) combining the biologically active substance with the starch solution under ~~such~~ conditions such that a composition in ~~the form of~~ a form selected from a solution, emulsion, or suspension of said substance in the starch solution is ~~formed~~ produced;

c) ~~mixing~~ adding to the composition obtained in step b) ~~with~~ an aqueous solution of a polymer having the ability of forming a two-phase aqueous system, thereby forming an emulsion of starch droplets which contain the biologically active substance as an inner phase in an outer phase of said polymer solution, wherein the polymer solution is added to the composition in at least two steps, in which at least one of the additions occurs after the emulsion has begun to be created;

d) causing or allowing the starch droplets obtained in step c) to gel into starch particles through the natural capacity of the starch to solidify;

e) drying the starch particles~~, preferably~~ after prior removal of said outer phase through washing; and

f) optionally applying a releasing-controlling shell of a biocompatible and biodegradable polymer~~, preferably~~ by air suspension technology[,] to the dried starch particles.

2. (Currently amended) [A] The process according to claim 1, in which the starch has a purity of at most 20 µg~~, preferably at most 10 µg, and more preferably at most 5 µg,~~ amino acid nitrogen per [g] gram dry weight of starch.

3. (Currently amended) [A] The process according to claim 1, in which the starch has an amylopectin content with said reduced molecular weight exceeding 95% by weight~~, preferably exceeding 98% by weight~~.

4. (Currently amended) [A] The process according to claim 1, in which the molecular weight of said amylopectin is reduced such that at least 80% of the ~~material~~ amylopectin is within the range of 100-4,000 kDa~~, preferably 200-1,000 kDa, and more preferably 300-600 kDa~~.

5. (Currently amended) [A] The process according to claim 1, in which the starch is ~~such that it can be~~ dissolved in a concentration exceeding 25% by weight in water.

6. (Canceled)

7. (Currently amended) [A] The process according to claim 1, in which the starch has an endotoxin content of less than 25 EU/g and contains less than 100 microorganisms per gram.

8. (Currently amended) [A] The process according to claim 1, in which the starch is essentially purified from surface-localized proteins, lipids and endotoxins by ~~means of~~ washing with aqueous alkali solution, reduced in molecular weight by ~~means of~~ shearing, and purified from internal proteins by ~~means of~~ ion exchange chromatography~~, preferably anion exchange chromatography~~.

9. (Currently amended) [A] The process according to claim 1, in which, in step a), 2-15% by weight amylose is also used as a starch, having an average molecular weight within the

range of 2.5-70 kDa, ~~preferably 5-45 kDA,~~ in which the percentage share by weight is calculated based on the basis of dry weight of starch.

10. (Currently amended) [A] The process according to claim 1, in which, in step a), a solution is prepared having a starch concentration of at least 30% by weight.

11. (Currently amended) [A] The process according to claim 1, in which, in step a), a solution is prepared having a starch concentration of at most 50% by weight~~, preferably at most 45% by weight~~.

12. (Currently amended) [A] The process according to claim 1, in which the aqueous starch solution in step a) is prepared with accompanying autoclaving of the same.

13. (Currently amended) [A] The process according to claim 1, in which, in step b), the active substance is combined with the starch solution at a temperature of at most 60°C~~, preferably 20-45°C, especially 30-37°C~~.

14. (Currently amended) [A] The process according to claim 1, in which, in step b), a composition is formed in which the weight ratio between starch and biologically active substance is within [the] a range [of] selected from 3:1 to 10,000:1~~, preferably~~ or 3:1 to 100:1.

15. (Currently amended) [A] The process according to claim 1, in which, in step c), the polymer ~~is used in a concentration~~ is present in said aqueous solution in a concentration of at least 20% by weight~~, preferably at least 30% by weight~~.

16. (Currently amended) [A] The process according to claim 1, in which, in step c), the polymer ~~is used in a concentration~~ is present in said aqueous solution in a concentration of at most 45% by weight~~, preferably 30-40% by weight~~.

17. (Currently amended) [A] The process according to claim 1, in which the mixing in step c) is performed at a temperature within the range of 4-50°C~~, preferably 10-40°C, especially 10-37°C~~.

18. (Currently amended) [A] The process according to claim 1, in which mixing in step c) is performed with the aid of at least one static mixer.

19. (Canceled)

20. (Currently amended) [A] The process according to claim 1, in which, in step c), polyethylene glycol is used as the aqueous polymer.

21. (Currently amended) [A] The process according to claim 20, in which the polyethylene glycol has an average molecular weight of 5-35 kDa~~, preferably 15-25 kDa, especially about 20 kDa~~.

22. (Currently amended) [A] The process according to claim 1, in which the solidification in step d) is performed at at least two temperatures, comprising an initiation temperature and a termination temperature, wherein ~~in which~~ the initiation ~~is effected at a lower~~ temperature is lower than the termination temperature.

23. (Currently amended) [A] The process according to claim 22, in which the solidification is initiated at a temperature within the range of 1-20°C~~, preferably 1-10°C, especially around 4°C,~~ and is terminated at a temperature within the range of 20-55°C~~, preferably 25-40°C, especially around 37°C~~.

24. (Currently amended) [A] The process according to claim 1, in which the drying in step e) ~~is performed in the form of~~ is selected from spray drying, freeze-drying, or vacuum drying~~, preferably freeze-drying~~.

25. (Currently amended) [A] The process according to claim 1, in which, ~~as~~ the biologically active substance~~, a substance is incorporated which is chosen~~ is selected from the group consisting of proteins, recombinantly produced proteins, peptides, polypeptides, polynucleotides and polysaccharides~~, especially recombinantly produced proteins~~.

26. (Currently amended) [A] The process according to claim 1, in which ~~said~~ the biologically active substance is selected from the group consisting of growth factors, insulin,

erythropoietin, interferon α, interferon β, interferon γ, blood coagulation factor ~~factors~~ V, blood coagulation factor VI, blood coagulation factor VII, blood coagulation factor VIII, blood coagulation factor IX, blood coagulation factor X, blood coagulation factor XI, blood coagulation factor XII, [and] blood coagulation factor XIII, protein C, glucagon-like peptide 1, [or] glucagon-like peptide 2, C-peptide, epidermal growth factor, growth hormone, LHRH-analogues, civamide, macrophage colony-stimulating factor, granulocyte[,] colony-stimulating factor, leptin and interleukin~~, or an analogue or derivate of any one thereof, which possesses essentially the same pharmacological activity as the patent substance or improved pharmacological activity as compared thereto~~.

27. (Currently amended) [A] The process according to claim 1, in which, in step c), starch droplets are formed, ~~which give the size required for the microparticles, preferably~~ said starch droplets providing microparticles comprising a mean particle diameter, in the dry state, within the range of 10-200 μm~~, preferably 20-100 μm, more preferably 20-80 μm~~.

28. (Currently amended) [A] The process according to claim 1, in which, after step d), the microparticles are washed through filtration, and optionally sieved in order to obtain the desired particle size distribution.

29.-47 (Canceled)

48. (Currently amended) [A] The process according [the] to claim 2, in which the starch has an amylopectin content with said reduced molecular weight exceeding 95% by weight.

49. (Canceled)

50. (New) The process according to claim 1, in which the starch has a purity of at most 10 μg amino acid nitrogen per gram dry weight of starch.

51. (New) The process according to claim 1, in which the starch has a purity of at most 5 μg amino acid nitrogen per gram dry weight of starch.

52. (New) The process according to claim 1, in which the starch has an amylopectin content with said reduced molecular weight exceeding 98% by weight.

53. (New) The process according to claim 1, in which the molecular weight of said amylopectin is reduced such that at least 80% of the amylopectin is within the range of 200-1,000 kDa.

54. (New) The process according to claim 1, in which the molecular weight of said amylopectin is reduced such that at least 80% of the amylopectin is within the range of 300-600 kDa.

55. (New) The process according to claim 8, in which the starch is purified from internal proteins by anion exchange chromatography.

56. (New) The process according to claim 1, in which, in step a), 2-15% by weight amylose is also used as a starch, having an average molecular weight within the range of 5-45 kDA, in which the percentage share by weight is calculated based on the basis of dry weight of starch.

57. (New) The process according to claim 1, in which, in step a), a solution is prepared having a starch concentration of at most 45% by weight.

58. (New) The process according to claim 1, in which, in step b), the active substance is combined with the starch solution at a temperature in the range of 20-45°C.

59. (New) The process according to claim 1, in which, in step b), the active substance is combined with the starch solution at a temperature in the range of 30-37°C.

60. (New) The process according to claim 20, in which the polyethylene glycol has an average molecular weight of 15-25 kDa.

61. (New) The process according to claim 20, in which the polyethylene glycol has an average molecular weight of about 20 kDa.

62. (New) The process according to claim 22, in which the solidification is initiated at a temperature within the range of 1-10°C and is terminated at a temperature within the range of 25-40°C.

63. (New) The process according to claim 22, in which the solidification is initiated at a temperature of about 4°C and is terminated at a temperature of about 37°C.

64. (New) The process according to claim 1, in which, in step c), starch droplets are formed, said starch droplets providing microparticles comprising a mean particle diameter, in the dry state, within the range of 20-100 μm.

65. (New) The process according to claim 1, in which, in step c), starch droplets are formed, said starch droplets providing microparticles comprising a mean particle diameter, in the dry state, within the range of 20-80 μm.

66. (New) The process according to claim 2, in which the starch has an amylopectin content with said reduced molecular weight exceeding 98% by weight.